REMARKS

Claims 1-2 and 4 are currently pending in this application. Claim 1 has been amended to incorporate the language of former claim 3, which has been canceled. Claim 1 has also been amended to recite that the composition is an inhalable powder composition that is delivered in a single dose from a reservoir made of synthetic plastic. Support for this amendment is found, e.g., in the specification on page 10, lines 15-18. Claim 4 has been amended to correct dependency now that claim 3 has been canceled. Claim 5 has been added to recite the type of synthetic plastic. Support for this claim is found in the specification on page 11, lines 8-9. No new matter is presented by way of this amendment.

Rejection under 35 U.S.C. § 103:

Claims 1-4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 02/36163 in view of U.S. Patent No. 6,623,760. Applicants respectfully traverse.

The presently-claimed invention is directed to an inhalable powder containing a highly efficacious active substance that can be administered in a single dose with the lowest possible variability during metering. According to the specification on page 3, line 28, to page 4, line 6, the reservoir from which the inhalable powder is dispersed plays an important role in the administration of active substance. Poor emptying characteristics of the reservoir containing active compound will result in small amounts of powder formulation being released. This in turn requires a significant amount of inhalable powder to be loaded into the reservoir, most of which will be left in the reservoir, in order that the appropriate therapeutic dose is administered to the patient. Thus, one object of the invention is to minimize the interaction between reservoir and active substance such that nearly all of active compound loaded into the reservoir is emptied, resulting in accurate and reproducible (low variability) metering. Amended claim 1 reflects the inhalable powder composition when delivered as a single dose from a powder reservoir composed of a material made from a synthetic plastic.

Neither WO 02/36163 (English-language equivalent CA 2436537) nor US 6,623,760 discloses inhalable powders with elements according to claim 1 delivered as a single dose from a reservoir composed of material made from synthetic plastics. For example, WO 02/36163 discloses compositions based on tiotropium salts and antihistamines. The Examiner points to page 10, lines 2-3, for discussion of particle size. This citation however refers to the particle size of the active substance and not that of the excipient as described in currently pending claim 1. The Examiner also points to column 7, lines 56-67, to column 8, line 36 in US 6,623,760 for discussion of particle size distribution when forming agglomerates. This citation refers to a general discussion of solid carrier particles, its size overall and the preferred amount of convertible amorphous content of the solid carrier. In fact, US 6,623,760 is largely directed to capitalizing on the convertible amorphous content imparted to the solid carrier and its subsequent conversion to crystalline form as a means of binding the agglomerate (see column 7, lines 49-54). Unlike the present invention, there is no discussion of fine particle content/size comprising the excipient in the inhalable powder composition. Furthermore, neither WO 02/36163 nor US 6,623,760 discloses delivery of the composition as a single dose from a reservoir composed of material made from synthetic plastics. Because elements of independent claim 1 are lacking in both WO 02/36163 nor US 6,623,760, the combination of these references do not render the instant application obvious. Applicants respectfully request withdrawal of this rejection.

Applicants respectfully submit that all the pending claims are allowable. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

Respectfully submitted,
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